162428101

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on **December 29, 2000** 

Name: C. Fong

By: C. Forg

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gary D. GLICK, et al.

Application Serial No. 09

Filed: November 8, 2000

For:

THERAPEUTIC APPLICATIONS

OF PRO-APOPTOTIC BENZODIAZEPINES

Art Unit: Unassigned

Examiner: Unassigned

Attorney's Docket No. 128019-203801

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been

cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No statement under 37 C.F.R. § 1.97(e) or fee is required.
- □ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.
  - □ a. I hereby state that each item of information contained in this Information

    Disclosure Statement was cited in a communication from a foreign patent office
    in a counterpart foreign application not more than three months prior to the
    filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
  - □ b. I hereby state that no item of information in this Information Disclosure

    Statement was cited in a communication from a foreign patent office in a

    counterpart foreign application, and, to my knowledge after making reasonable
    inquiry, no item of information contained in this Information Disclosure

    Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more
    than three months prior to the filing of this Information Disclosure Statement.

    37 C.F.R. § 1.97(e)(2).
  - □ c. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p).
- □ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. It is hereby requested that the Information Disclosure Statement be considered. Attached is our Check No. \_\_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(i).
  - □ a. I hereby state that each item of information contained in this Information

    Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
  - □ b. I hereby state that no item of information in this Information Disclosure

    Statement was cited in a communication from a foreign patent office in a

    counterpart foreign application, and, to my knowledge after making reasonable

RECEIVE

inquiry, no item of information contained in this Information Disclosure

Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more
than three months prior to the filing of this Information Disclosure Statement.

37 C.F.R. § 1.97(e)(2).

<b>□</b> 4.	Relevance of the non-English language document(s) is discussed in the present specification.  The document(s) was/were cited in a corresponding foreign application. An English					
	ER 2					
<b>□</b> 5.	The document(s) was/were cited in a corresponding foreign application. An English					
	language version of the foreign search report is attached for the Examiner's information					
□ 6.	A concise explanation of the relevance of the non-English language document(s)					
	appears below:					
<b>□</b> 7.	The Examiner's attention is directed to co-pending U.S. Patent Application No.					
	, filed, which is directed to related technical subject matter. The					
	identification of this U.S. Patent Application is not to be construed as a waiver of					
	secrecy as to that application now or upon issuance of the present application as a					
	patent. The Examiner is respectfully requested to consider the cited application and the					
	art cited therein during examination.					
□ 8.	Copies of the documents were cited by or submitted to the Office in Application No.					
	, filed, which is relied upon for an earlier filing date under					
	35 S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).					
	It is respectfully requested that the Examiner initial and return a copy of the enclosed					
PTO-14	49, and to indicate in the official file wrapper of this patent application that the					
docume	ents have been considered.					
	The U.S. Patent and Trademark Office is hereby authorized to charge any fee					
deficiency, or credit any overpayment, to our Deposit Account No. 50-0974.						

Date: December 29, 2000

Baker & McKenzie 660 Hansen Way Palo Alto, California 94304 (650) 856-2400 Respectfully submitted,

Antoinette F. Konski (Reg. No. 34,202)

PTO/SB/08 (2/92) Sheet 1 of 3

Application Serial No. 09/700.101

Applicant(s) INFORMATION DISCLOSURE STATEMENT Gary D. GLICK, et al. Filing Date: November 8, 2000 Group Art Unit: Unassigned (use several sheets if necessary) U.S. PATENT DOCUMENTS **Examiner** Ref. Date Document No. Name Class Subclass Filing Date Initials No. (if appropriate) 1. 02/28/1978 4,076,823 Wade, et al. 2. 08/29/1978 4,110,337 Szarvasi 3. Klaubert, et al. 01/22/1985 4.495.101 4. 06/14/1988 4,751,223 Glamkowski, et al. 5. 08/20/1991 5,041,438 Hsu 6. 06/28/1994 5,324,726 Bock, et al. 7. 01/28/1997 5.597.915 Chambers, et & 07/07/1998 5.776.946 8. McGeer, et al. 9. 01/19/1999 5.861.380 Gyorkos, et al. 10. 12/21/1999 6,004,942 Firestein, et al. 11. 06/27/2000 6.080.588 Glick FOREIGN PATENT DOCUMENTS Examiner Ref. Date Document No. Name **Translation** Class **Subclass** Initials No. YES NO 12. 06/04/2000 WO 00/19200 PCT OTHER DOCUMENTS (including author, title, date, pertinent pages, etc.) Examiner Ref. Title Initials No. Adachi, M., et al., "Aberrant Transcription Caused by the Insertion of an Early Transposable Element in an Intron of the 13. Fas Antigen Gene of *Ipr* Mice," *Proc. Natl. Acad. Sci. USA* – <u>90</u>:1756-1760 (1993) 14. Adelman, N.E., et al., "Treatment of (NZB X NZW)F1 Disease with Anti-I-A Monoclonal Antibodies," J. Exp. Med. -<u>158</u>:1350-1355 (1983) 15. Baader, S.L., et al., "Uptake and Cytotoxicity of Ascorbic Acid and Dehydroascorbic Acid in Neuroblastoma (SK-N-SH) and Neuroectodermal (SK-N-LO) Cells," Anticancer Research - 14:221-228 (1994) Beale, P.J., et al., "BCL-2 Family Protein Expression and Platinum Drug Resistance in Ovarian Carcinoma," British 16. Journal of Cancer - 82(2):436-440 (2000) 17. Boojamra, C.G., et al., "Solid-Phase Synthesis of 1,4-Benzodiazepine-2,5-Diones. Library Preparation and Demonstration of Synthesis Generality," J. Org. Chem. – 62:1240-1256 (1997) 18. Bunin, B.A., et al., "A General and Expedient Method for the Solid-Phase Synthesis of 1,4-Benzodiazepine Derivatives," J. Am. Chem. Soc. - 114:10997-10998 (1992) 19. Bunin, B.A., et al., "The Combinatorial Synthesis and Chemical and Biological Evaluation of a 1,4-Benzodiazepine Library," Proc. Natl. Acad. Sci. USA - 91:7408-4712 (1994) 20. Chumakov, A.M., et al., "Analysis of p53 Transactivation Through High-Affinity Binding Sites," Oncogene - 8:3005-3011 (1993)21. Cohen, P.L., et al., "Lpr and gld: Single Gene Models of Systemic Autoimmunity and Lymphoproliferative Disease," Annu. Rev. Immunol. - 9:243-269 (1991) 22. Crabtree, R.H., "A New Type of Hydrogen Bond," Science – 282:2000-2001 (1998) 23. Desoize, B., "Anticancer Drug Resistance and Inhibition of Apoptosis," Anicancer Research – 14:2291-2294 (1994) **EXAMINER: DATE CONSIDERED:** EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conforma not considered. Include a copy of this form with next communication to applicant.

Attorney's Docket No. 128019-203801

Form PTO-1449

154157.1

193696v1

	Form PTO-1449	Attorney's Docket No. 128019-203801 Application Serial No. 102700,101							
		Applicant(s)							
INFORM	ATION DISCLOSURE STATEMENT	Gary D. GLICK, et al.							
		Filing Date: November 8, 2000 Group Art it: Unassigned							
(us	e several sheets if necessary)	DOCUMENTS (Continuation)							
	(including aut	hor title date pertinent pages, etc.)							
24	Doble, A., et al., "Labelling of Periphe	ral-Type Benzodiazepine Binding Sites in Human Brain with [3H]PK 11195:							
	Anatomical and Subcellular Distributi	on," Brain Research Bulltetin – 18:49-61 (1987)							
25	5. Donadio, J.V., et al., "Immunosuppres 21(3):239-250 (1993)	ssive Drug Therapy in Lupus Nephritis," American Journal of Kidney Diseases –							
26	Frmak T.H. et al. "Treatment of Muri	ne Lupus with Monoclonal Antibody to L3T4," Laboratory Investigation							
2	61/4\.447_456 (1080)								
27	Gallant   F et al "Incidence and Nat	tural History of Cytomegalovirus Disease in Patients with Advanced Human							
	Immunodeficiency Virus Disease Trea	ated with Zidovudine," The Journal of Infectious Diseases -306:1223-1227 (1992)							
28	of Biological Chemistry - 273(49):326	Garcia-Calvo, M., et al. "Inhibition of Human Caspases by Peptide-Based and Macromolecular Inhibitors," The Journal of Biological Chemistry – 273(49):32608-32613 (1998)							
29	Gorczyca, W., et al., "Induction of DN	Gorczyca, W., et al., "Induction of DNA Strand Breaks Associated with Apoptosis During Treatment of Leukemias,"							
3(	Leukemia – 7(5):659-670 (1993) C	vith Recombinant Tumor Necrosis Factor-α in Autoimmune NZB/NZW F <sub>1</sub> Mice,"							
3	Clinical Immunology and Immunopat	hology – 52:421-434 (1989) 🗸							
3	Cordon EM at al "Applications of	Combinatorial Technologies to Drug Discovery. 2. Combinatorial Organic							
	Synthesis, Library Screening Strateg	ies, and Future Directions," <i>Journal of Medicinal Chemistry</i> – <u>37(</u> 10):1385-1401							
	(1994)	Land Other Immunocurrencing Drugs on Immuno Disorders and							
3	Noonlasia in NZR/NZW Mice." Arthrift	Hahn, B.H., et al., "Influence of Cyclophosphamide and Other Immunosuppressive Drugs on Immune Disorders and Neoplasia in NZB/NZW Mice," Arthritis and Rheumatism – 18(2):145-152 (1975)							
3	3 Hang I et al. "A Spontaneous Rhe	Hang Let al. "A Spontaneous Rheumatoid Arthritis-Like Disease in MRL/1 Mice," J. Exp. Med 155:1690-1701 (1962)							
	4. Horowitz, R.E., et al., "Cyclophospha	Horowitz, R.E., et al., "Cyclophosphamide Treatment of Mouse Systemic Lupus Erythematosus," Laboratory							
	Investigation - 21(3):199-206 (1969)	Investigation - 21(3):199-206 (1969) <li>Itoh, N., et al., "The Polypeptide Encoded by the cDNA for Human Cell Surface Antigen Fas Can Mediate Apoptosis,"</li>							
3	5. Itoh, N., et al., "The Polypeptide Enco	oded by the CDNA for Human Cell Surface Antigent as Oan Mediate Apoptosis,							
	Cell – 66:233-243 (1991)   Koopman, W. L. et al. "The MRI -lpr/	pr Mouse. A Model for the Study of Rheumatoid Arthritis," Scand. J.							
3	Phaymatology - Suppl 75:284-289 (1988)								
3	37. Korsmeyer, S.J., "Bcl-2 Initiates a New Category of Oncogenes: Regulators of Cell Death," <i>Blood</i> – <u>80(4):879-886</u>								
	(1992)								
3	Liu, J.R., et al., "Bcl-x∟ is Expressed in Ovarian Carcinoma and Modulates Chemotherapy-Induced Apoptosis," <i>Gynecologic Oncology</i> – 70:398-403 (1998) ✓								
39. Los, M., et al., "The Role of Caspases in Development, Immunity, and Apoptotic Signal Transduction: Lessons									
	Knockout Mice." Immunity – 10:629-639 (1999)								
	0. Luria, et al., "General Viology – 3 <sup>rd</sup> e	Luria, et al., "General Viology – 3rd edition, pp. 436-446 (1978) – Eds. John Wiley & Sons, New York							
4	Marino, M., et al., "Prevention of Systemic Lupus Erythematosus in MRL/Ipr Mice by Administration of an Immunoglobulin-Binding peptide," Nature Biotechnology – 18:735-739 (2000)								
	12. McDonnell, T.J., et al., "Progession	McDonnell, T.J., et al., "Progession from Lymphoid Hyperplasia to High-Grade Malignant Lymphoma in Mice							
	Transgenic for the t/14:18) " Nature:								
- 1	13. Nagata, S., "Human Autoimmune Ly	mphoproliferative Syndrome, a Defect in the Apoptosis-Inducing Fas Receptor: A							
	Locan from the Mouse Model " I b	Leason from the Mouse Model " I Hum Genet - 43:2-8 (1998)							
	Okuyama, H., et al., "Analysis of Def	Okuyama, H., et al., "Analysis of Defective Delayed-Type Hypersensitivity in Autoimmune Mice Bearing Ipr Gene," Clin.							
	Exp. Immunol 63:87-94 (1986)  Okuyama, H., et al., "Effect of Cyclophosphamide Pretreatment on Defective Delayed-Type Hypersensitivity in								
	45. Okuyama, H., et al., "Effect of Cyclophosphamide Pretreatment on Derective Delayed-Type Hypersensitivity III  Autoimmune-Prone MRL Mice," Int. Arch. Allergy Appl. Immunol. – 88:394-401 (1989)								
<u> </u>	·								
EXAMINER	:	DATE CONSIDERED:							

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conforma not considered. Include a copy of this form with next communication to applicant.

154157.1

193696v1

Form PTO-1449			Attorney's Docket No. 1	28019-203801	Application Serial No. 09/700,101				
INFO	ORMATIC	ON DISCLOSURE STATEMENT	Applicant(s)  Gary D. GLICK, et al.						
		SIL DIOCEOGORE STATEMENT			, n, et al.				
	(use se	veral sheets if necessary)	Filing Date: November	8, 2000	Group Art Unit: Unassigned				
		OTHER	DOCUMENTS (Continua	tion)	E. of the Carlotte				
	T 40	(including author, title, date, pertinent pages, etc.)							
	46.	Ozols, R.F., "Paclitaxel Plus Carboplatin in the Treatment of Ovarian Cancer," Seminars in Oncology – <u>26(1)(Supp.</u> 2):84-89 (1999)							
	47.		K.E., et al., "Characterisation of the <i>P53</i> Status, BCL-2 Expression and Radiation and Platinum Drug Sensitivity						
		of a Panel of Human Ovarian Cancer C	of Human Ovarian Cancer Cell Lines," <i>Int. J. Cancer</i> – 77:913-918 (1998)						
	48.	Raynaud, F.I., et al., "Intracellular Metabolism of the Orally Active Platinum Drug JM216: Influence of Glutathione Levels," Br. J. Cancer – 74(3):380-386 (1996)  Russell, J.H., et al., "Mature T Cells of Autoimmune Ipr/Ipr Mice have a Defect in Antigen-Stimulated Suicide," Proc. Natl. Acad. Sci. USA – 90:4409-4413 (1993)  Sakata, K., et al., "Role of Fas/FasL Interaction in Physiology and Pathology: The Good and the Bad," Clinical Immunology and Immunopathology – 87(1):1-7 (1998)							
	49.								
	50.								
OIP &	51.	Sandstrom, P.A., et al., "Autocrine Production of Extracellular Catalase Prevents Apoptosis of the Human CEM T-Cell Line in Serum-Free Medium," <i>Proc. Natl. Acad. Sci. USA</i> – 90:4708-4712 (1993)							
	52.	Schoemaker, H., et al., "Specific High-Affinity Binding Sites for [3H]Ro5-4864 in Rat Brain and Kidney," The Journal of Pharmacology and Experimental Therapeutics – 225(1):61-69 (1983)							
JAN 0 8 200		Schwab, M., et al., "Amplified DNA with	o, M., et al., "Amplified DNA with Limited Homology to <i>myc</i> Cellular Oncogene is Shared by Human lastoma Cell Lines and a Neuroblastoma Tumour," <i>Nature</i> – 305:245-248 (1983)						
· .	.54	Scott, C.F., et al., "Comparison of Antigen-Specific T Cell Responses in Autoimmune MRL/mp-lpr/lpr and MRL/mp-+/+							
& TRADEM!	55	Mice," The Journal of Immunology – 1	<u>32(</u> 2):633-639 (1984)						
	55.	Sentman, C.L., et al., "bcl-2 Inhibits Multiple Forms of Apoptosis but not Negative Selection in Thymocytes," Cell – 67:879-888 (1991)							
	56.	Sheppard, R.C., et al., "Acid-Labile Resin Linkage Agents for Use in Solid Phase Peptide Synthesis," Int. J. Peptide Protein Res. – 20:451-454 (1982)							
	57.	Stevens, S.Y., et al., "Non Nucleic Acid Chemistry," J. Am. Chem. Soc. – 118:1	Stevens, S.Y., et al., "Non Nucleic Acid Inhibitors of Protein-DNA Interactions Identified Through Combinatorial Chemistry," J. Am. Chem. Soc. – 118:10650-10651 (1996)						
	58.	Sugimoto, T., et al., "Determination of Cell Surface Membrane Antigens Common to Both Human Neuroblastoma and							
	50	Leukemia-Lymphoma Cell Lines by a Panel of 38 Monoclonal Antibodies," JNCI – 73(1):51-57 (1984)							
	59. Swanson, P.C.,et al., "High Resolution Epitope Mapping of an Anti-DNA Autoantibody Using Model DNA Ligands," Immunology – 152(5):2601-2612 (1994)								
<ul> <li>Swanson, P.C., et al., "Ligand Recognition by Murine Anti-DNA Autoantibodies," J. Clin. Invest. – 97(7):1748 (1996)</li> <li>Takahashi, T., et al., "Generalized Lymphoproliferative Disease in Mice, Caused by a Point Mutation in the Facell –76:969-976 (1994)</li> </ul>									
							62.	Theofilopoulous, A.N., et al., "Murine Models of Systemic Lupus Erythematosus," Advances in Immunology – 37:269-390 (1985)	
	ice - <u>267</u> :1456-1462 (1995)								
64. Watanabe-Fukunaga, R., et al., "Lymphoproliferation Disorder in Mice Explained by Defects in Fas An Mediates Apoptosis," <i>Nature</i> – 356:314-317 (1992)									
	65.	White, E., "Life, Death, and the Pursuit	of Apoptosis," Genes & Development – <u>10</u> :1-15 (1996)						
	66.	Wu, G.Y., et al., "Receptor-Mediated in	in Vitro Gené Transformation by a Soluble DNA Carrier System." The Journal of						
	67.		e, A.H., "The Genetic Regulation of Apoptosis," Current Opinion in Genetics & Development – 5:97-104 (1995)						
	68.	Zamzami, N., et al., "Mitochondrial Control of Nuclear Apoptosis," J. Exp. Med. – 183:1533-1544 (1996)							
	69.	Zoratti, M., et al., "The Mitochondrial Permeability Transition," Biochimica et Biophysica Acta – 1241:139-176 (1995)							
EXAMINE	R·		DATE CONS						

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conforma not considered. Include a copy of this form with next communication to applicant.

154157.1

193696v1